To: Mendez, Elizabeth[Mendez.Elizabeth@epa.gov]; Lowit, Anna[Lowit.Anna@epa.gov]; Metzger,

Michael[Metzger.Michael@epa.gov]; Vogel, Dana[Vogel.Dana@epa.gov]; Akerman, Gregory[Akerman.Gregory@epa.gov]

Cc: Miller, David[Miller, David]@epa.gov]; Liccione, John[Liccione.John@epa.gov]; Wilbur, Donald[Wilbur, Donald]@epa.gov]

From: Rickard, Kristin[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=925CB954711F47A3A3F44886F09AB44F-RURY, KRISTIN]

Sent: Mon 4/6/2020 7:36:34 PM (UTC)

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

red PC-080803 1-Apr-06.pdf

Albanito et al 2015.pdf

Atrazine HHRA Public Comments filted by HED.xlsx

WHO Study Reference Table.docx

Thanks Liz *

Just circling back to my sleuthing in the public comments and older atrazine documents. We didn't receive much in the way of public comments on the atrazine HHRA. I re-looked through the comments and didn't see anything resembling the citations in the letter forwarded by WHO.

Ex. 5 Deliberative Process (DP)

I also was able to pull the full text of the Albanito 2015 article and have attached it here.

Hope this helps! Please let me know if I can do anything additional.

Kristin Rickard Health Effects Division Office of Pesticide Programs Rickard.Kristin@epa.gov 703-347-0112

From: Mendez, Elizabeth < Mendez. Elizabeth@epa.gov>

Sent: Monday, April 06, 2020 2:47 PM

To: Rickard, Kristin <Rickard.Kristin@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Metzger, Michael

<Metzger.Michael@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>

Cc: Miller, David <Miller.DavidJ@epa.gov>; Liccione, John <Liccione.John@epa.gov>

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Hi Kristin,

I just knew that with your mad computer skills you'd be able to find most of these. I'm guessing

Ex. 5 Deliberative Process (DP)

nt ir

Elizabeth Mendez, Ph.D.

HED Senior Science Advisor

US EPA

Health Effects Div./Office of Pesticide Programs

Tel: 703-305-5453 Cell: 571-217-8150

From: Rickard, Kristin < Rickard. Kristin@epa.gov >

Sent: Monday, April 06, 2020 1:59 PM

To: Mendez, Elizabeth < Mendez. Elizabeth@epa.gov>; Lowit, Anna < Lowit. Anna@epa.gov>; Metzger, Michael

<<u>Metzger.Michael@epa.gov</u>>; Vogel, Dana <<u>Vogel.Dana@epa.gov</u>>; Akerman, Gregory <<u>Akerman.Gregory@epa.gov</u>>

Cc: Miller, David < Miller.DavidJ@epa.gov >; Liccione, John < Liccione.John@epa.gov >

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Hi Liz,

Thanks – I tried to quickly go through the SAP materials – updated table below. If you think you recognize any reference that I couldn't find or if you have suggestions on where else to look, let me know!

| Type of Study | Reference provided in Sign-on Letter | Included in Agency RA Decisions? |
|---------------|---|--|
| Epidemiology | Beane Freeman et al 2011 | Included in 2011 SAP materials Appendix B Also included in most recent atrazine RA |
| | Agopian et al. 2013a, 2013b | • Included in Agency epidemiology review of atrazine (D447696) |
| | Almberg et al. 2018 | RA was completed in July 2018 – this is in the August 2018 version of International Journal of Environmental Research and Public Health Not included in most recent atrazine RA |
| Toxicology | Albanito et al. 2015 | Most recent SAP was in 2011 Not in most recent atrazine RA |
| | Connor et al. 1996 | • In EDSP document |
| | Tennant et al. 1994 | Included in 2000 SAP materials |
| | Sanderson et al. 2001 | Included in the most recent atrazine RA Included in Appendix A of 2011 SAP materials |
| | SAP 2011 | Outcomes incorporated into most recent atrazine RA |
| | Wirbisky and Freeman 2015 | Not in most recent atrazine RA – latest SAP is 2011, where else should I check? |
| | Pogrmic-Majkic et al. 2016 | Not in most recent atrazine RA – latest SAP is 2011 – where else should I check? |
| | Gojmerac et al. 1994 | Not in most recent atrazine RA. I couldn't find in the SAP materials but maybe I missed it? |
| | Gojmerac et al. 1999 | Included in NRDC public comments to 2003 SAP, but did not see a direct Agency reference or response. |

| Gojmerac et al. 2004 | • Included in 2010 SAP |
|----------------------|--|
| Torres et al. 1992 | • Included in 2000 SAP materials |
| Zhu et al. 2010 | • EFED? |
| Adeyemi et al. 2015 | |
| Wirbisky et al. 2016 | |
| Gao et al. 2016 | |
| | Torres et al. 1992 Zhu et al. 2010 Adeyemi et al. 2015 Wirbisky et al. 2016 |

Kristin Rickard Health Effects Division Office of Pesticide Programs Rickard.Kristin@epa.gov 703-347-0112

From: Mendez, Elizabeth < Mendez. Elizabeth@epa.gov >

Sent: Monday, April 06, 2020 11:52 AM

To: Rickard, Kristin < Rickard.Kristin@epa.gov >; Lowit, Anna < Lowit.Anna@epa.gov >; Metzger, Michael

<Metzger.Michael@epa.gov>; Vogel, Dana <Vogel.Dana@epa.gov>; Akerman, Gregory <Akerman.Gregory@epa.gov>

Cc: Miller, David <Miller.DavidJ@epa.gov>; Liccione, John <Liccione.John@epa.gov>

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Team,

I think some of these studies were evaluated and incorporated into the SAP white papers. You might want to check in those documents. -- Liz

Elizabeth Mendez, Ph.D.

HED Senior Science Advisor

US EPA

Health Effects Div./Office of Pesticide Programs

Tel: 703-305-5453 Cell: 571-217-8150

From: Rickard, Kristin < <u>Rickard.Kristin@epa.gov</u>>

Sent: Monday, April 06, 2020 10:48 AM

To: Lowit, Anna <<u>Lowit.Anna@epa.gov</u>>; Metzger, Michael <<u>Metzger.Michael@epa.gov</u>>; Vogel, Dana <<u>Vogel.Dana@epa.gov</u>>;

Akerman, Gregory < Akerman. Gregory@epa.gov>; Mendez, Elizabeth < Mendez. Elizabeth@epa.gov>

Cc: Miller, David < Miller. David J@epa.gov >; Liccione, John < Liccione. John@epa.gov >

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Hi Anna (et. al),

Ex. 5 Deliberative Process (DP)

Hope this helps a little bit! Let me know if you need more information.

Kristin Rickard
Health Effects Division
Office of Pesticide Programs
Rickard.Kristin@epa.gov
703-347-0112

From: Lowit, Anna < Lowit. Anna@epa.gov > Sent: Monday, April 06, 2020 9:01 AM

To: Metzger, Michael < Metzger. Michael@epa.gov >; Rickard, Kristin < Rickard. Kristin@epa.gov >; Vogel, Dana

<<u>Vogel.Dana@epa.gov</u>>; Akerman, Gregory <<u>Akerman.Gregory@epa.gov</u>>; Mendez, Elizabeth <<u>Mendez.Elizabeth@epa.gov</u>>

Subject: FW: [EXT] Re: Seeking feedback on atrazine + other updates.

More Qs from WHO on our risk assessment.

Anna B. Lowit

Senior Science Advisor Immediate Office Office of Pesticide Programs US Environmental Protection Agency w: +1 703-308-4135

w: +1 703-308-4135 c: +1 703-258-4209

From: DE FRANCE, Jennifer <defrancej@who.int>

Sent: Monday, April 06, 2020 6:41 AM To: Lowit, Anna < Lowit. Anna@epa.gov>

Cc: Ohanian, Edward < Ohanian. Edward@epa.gov>

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Dear Anna

I was wondering if you could comment on whether EPA assessed a number of studies mentioned in the below mentioned letter sent to WHO and provide any comments on the studies (e.g. low quality, inadequate for RA purposes etc.). I've attached this letter which includes a bullet of studies they think supports their assessment that the WHO guideline value of 100 ug/L for atrazine is inadequately protective of human health with a reference list.

Also are you aware if EPA plans to update the MCL based on your office's recent assessment?

I realize you must be very busy during this time. Any further help you can provide would be gratefully appreciated.

Many thanks.

Jennifer

From: DE FRANCE, Jennifer Sent: 24 March 2020 17:42

To: Lowit, Anna < Lowit. Anna@epa.gov>

Cc: Ohanian, Edward < Ohanian. Edward@epa.gov >

Subject: Re: [EXT] Re: Seeking feedback on atrazine + other updates.

Thanks so much Anna

The MCL is quite a bit lower than the DWLOC where residential exposure is not a concern. Is there a plan to update the MCL?

Given your recent assessment, would you mind if I sent some info on the concerns raised by the NGO to get your insights on this?

Best regards Jennifer

Given your recent assessment can

On 24 Mar 2020, at 14:35, Lowit, Anna < Lowit. Anna@epa.gov > wrote:

Jennifer

Responses from my team in purple.

Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency

w: +1 703-308-4135 c: +1 703-258-4209

Begin forwarded message:

From: "DE FRANCE, Jennifer" < defrancej@who.int >

Date: March 24, 2020 at 5:54:39 AM EDT **To:** "Lowit, Anna" <Lowit.Anna@epa.gov>

Cc: "Ohanian, Edward" < Ohanian. Edward@epa.gov>

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Dear Anna

Sorry for the delay in responding. I'm finding it more and more difficult to stay on top of work, balancing this with homeschooling my son. I hope you and your family are well during this time.

Thank you for the detailed response – this is very helpful. I had a few comments and questions in green below. Can you kindly review when you get a chance?

Many thanks

Jennifer

From: Lowit, Anna <Lowit.Anna@epa.gov>

Sent: 20 March 2020 19:51

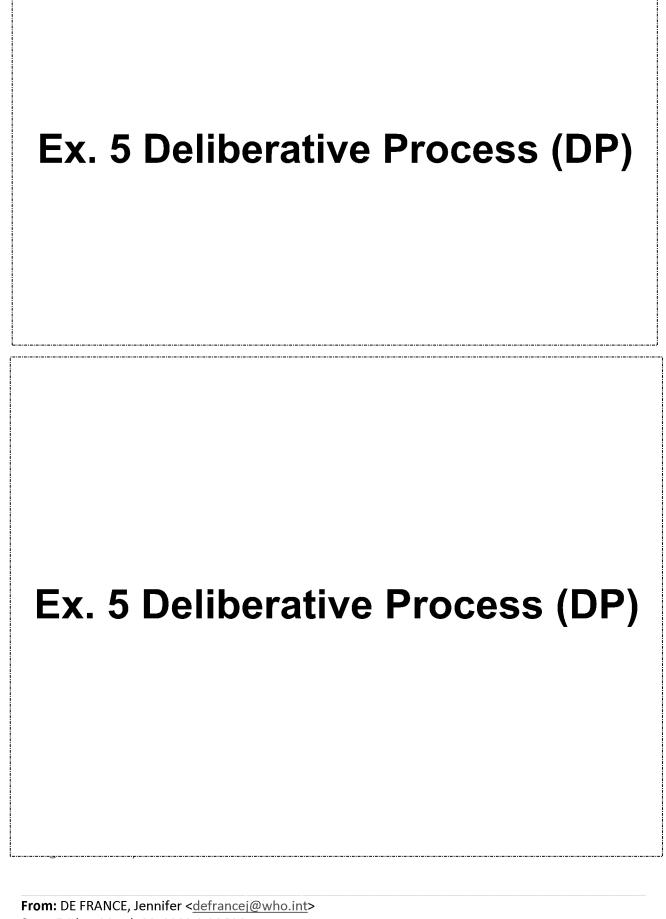
To: DE FRANCE, Jennifer <defrancej@who.int>; Ohanian, Edward <Ohanian.Edward@epa.gov>

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Jennfier: responses in red from our atrazine team.

Anna

Ex. 5 Deliberative Process (DP)



Sent: Friday, March 20, 2020 1:14 PM

To: Ohanian, Edward < Ohanian. Edward@epa.gov >; Lowit, Anna < Lowit. Anna@epa.gov >

Subject: RE: [EXT] Re: Seeking feedback on atrazine + other updates.

Ex. 5 Deliberative Process (DP)

If I misunderstood any of the above, can you advise? I am not familiar with these documents and so I may have misunderstood some things from a quick glance.

Ex. 5 Deliberative Process (DP)

Big thanks.

Jennifer

From: Ohanian, Edward < Ohanian. Edward@epa.gov>

Sent: 20 March 2020 14:49

To: Lowit, Anna < Lowit. Anna@epa.gov>
Cc: DE FRANCE, Jennifer < defrancej@who.int>

Subject: [EXT] Re: Seeking feedback on atrazine + other updates.

Hi Anna,

Thank you so much. I thought so but needed your confirmation. Be well, Ed

Edward V. Ohanian, Ph.D.
Associate Director for Science
USEPA/Office of Water (MC: 4301T)
(202) 566-1117 (Voice)
(202) 566-0441(Fax)

On Mar 20, 2020, at 9:07 AM, Lowit, Anna < Lowit. Anna@epa.gov > wrote:

Hi Ed & Jennifer

Our risk assessments have been finalized. We are now in the risk mitigation phase of registration review. See below:

https://www.epa.gov/ingredients-used-pesticide-products/atrazine

Anna

Anna B. Lowit

Senior Science Advisor Immediate Office Office of Pesticide Programs US Environmental Protection Agency

w: +1 703-308-4135 c: +1 703-258-4209

From: Ohanian, Edward < Ohanian. Edward@epa.gov>

Sent: Friday, March 20, 2020 6:08 AM

To: Lowit, Anna < Lowit. Anna@epa.gov>
Cc: Jennifer DE FRANCE < defrancej@who.int>

Subject: Fwd: Seeking feedback on atrazine + other updates.

Hi Anna,

Can you help me address Jennifer's attached question? Thx. Ed

Edward V. Ohanian, Ph.D.
Associate Director for Science
USEPA/Office of Water (MC: 4301T)
(202) 566-1117 (Voice)
(202) 566-0441(Fax)

Begin forwarded message:

From: "DE FRANCE, Jennifer" < defrancej@who.int>

Date: March 20, 2020 at 2:18:32 AM EDT

To: "Ohanian, Edward" < Ohanian. Edward@epa.gov > Cc: "GORDON, Bruce Allan" < gordonb@who.int >

Subject: Re: Seeking feedback on atrazine + other updates.

Dear Ed

Thanks so much for coordinating this. EPA's input on this (+ wider work) is really important. Has the EPA/OPP risk assessment been finalised and if so can you send to us? I see the draft risk assessment on line.

Best regards Jennifer

On 19 Mar 2020, at 22:15, Ohanian, Edward < Ohanian. Edward@epa.gov > wrote:

Hi Bruce and Jennifer, I just checked it with our folks. It's very prudent to use EPA/OPP assessment. However, I will leave it to you if it will require further interface with JMPR before adopting a different approach. Be well, Ed

Edward V. Ohanian, Ph.D.
Associate Director for Science
USEPA/Office of Water (MC: 4301T)
(202) 566-1117 (Voice)
(202) 566-0441(Fax)

On Mar 19, 2020, at 12:56 PM, DE FRANCE, Jennifer <<u>defrancej@who.int</u>> wrote:

Super thanks Ed!!

On 19 Mar 2020, at 16:50, GORDON, Bruce Allan <gordonb@who.int> wrote:

Thank you Ed (as always)! Bruce

From: Ohanian, Edward

<Ohanian.Edward@epa.gov>
Sent: 19 March 2020 16:35
To: GORDON, Bruce Allan

<gordonb@who.int>
Cc: DE FRANCE, Jennifer

<defrancej@who.int>
Subject: Re: Seeking feedback on atrazine + other updates.

Bruce,

That's an excellent point. I had a similar reaction when I saw Joe's email. Meanwhile, we will be in contact with our pesticides office. Best, Ed

Edward V. Ohanian, Ph.D.
Associate Director for Science
USEPA/Office of Water (MC: 4301T)
(202) 566-1117 (Voice)
(202) 566-0441(Fax)

On Mar 19, 2020, at 11:26 AM, GORDON, Bruce Allan <gordonb@who.int> wrote:

Hi Joe,
The JMPR should be
given the opportunity
to reassess it and then
we won't have a
situation where we
have two WHO bodies
giving different
assessments. But there

is a good chance that they may not have the resources.... Best Bruce

From: Joseph Cotruvo
(AoI)

<joseph.cotruvo@veriz
on.net>
Sent: 19 March 2020
16:16
To: GORDON, Bruce
Allan

<gordonb@who.int>;
DE FRANCE, Jennifer

<defrancej@who.int>;
'asami@niph.go.jp'

<asami@niph.go.jp>; 'Carrier, Richard (HC/SC)'

<a href="mailto:<a hre

<u>.au</u>)' <<u>David.Cunliffe@sa.gov</u>

.au>; DAnglada, Lesley <<u>DAnglada.Lesley@epa</u> .gov>; Eckhardt Dr.,

Alexander

<<u>Alexander.Eckhardt@</u> <u>uba.de</u>>;

'andrew.humpage@big pond.com'

<andrew.humpage@bi gpond.com>;

'john.fawell@johnfawel l.co.uk'

<john.fawell@johnfawe
ll.co.uk>; Akihiko Hirose
<akihikoh@dranihs.net</pre>

>;

'Peter.Marsden@defra. gsi.gov.uk'

<<u>Peter.Marsden@defra</u> .gsi.gov.uk>;

'matsui@eng.hokudai.a c.jp'

<matsui@eng.hokudai. ac.jp>; Ohanian,

Edward

<<u>Ohanian.Edward@epa</u> .gov>; 'Ong Choon

Nam'

<ephocn@nus.edu.sg>;

Strong, Jamie

<<u>Strong.Jamie@epa.go</u>

v>; Testai Emanuela <emanuela.testai@iss.i t> Subject: Re: Seeking feedback on atrazine + other updates.

It would be appropriate to review atrazine, simazine and propazine at the same time. The cite in the Atrazine paragraph below has a very detailed and up to date analysis reviewed by their external Science Advisory Committee and released in 2018. . The Population Adjusted Dose that they arrived at for hydroxyatrazine chronic exposure was 0.067 mg/kg/day with a 100 safety factor. They concluded that atrazine and metabolites had similar tox. . That would be 2.4 mg/day for a 60 kg person. They concluded it was not a carcinogen.

It should not be difficult to update the GDWQ GV with the existing recent reviews. Are you required to run it thru JMPR?

Joe

On 3/19/2020 10:40 AM, GORDON, Bruce Allan wrote: Thanks Joe and Colleague s, would

be great

to get a simple steer/reco mmendati on from the group if any of this is credible enough for us to recomme nd reassessm ent to JMPR (and then the question is whether they will do it) Best, Bruce

From:

Joseph Cotruvo (Aol)

Ex. 6 Personal Privacy (PP)

Sent: 19

March

2020

14:49

To: DE

FRANCE,

Jennifer

<defrancej

@who.int

≥;

'<u>asami@ni</u>

ph.go.jp'

<asami@n

<u>iph.go.jp>;</u>

Ex. 6 Personal Privacy (PP)

'Carrier, Richard (HC/SC)' <richard.c arrier@ca nada.ca>; 'Cunliffe, David (Health) (David.Cu nliffe@sa. gov.au)' <<u>David.Cu</u> nliffe@sa. gov.au>; DAnglada, Lesley <DAnglad a.Lesley@ epa.gov>; Eckhardt Dr., Alexander <Alexande r.Eckhardt @uba.de> 'andrew.h umpage@ bigpond.c <u>om</u>' <andrew. humpage @bigpond .com>; 'john.fawe <u>ll@johnfa</u> well.co.uk' <john.faw ell@johnf awell.co.u <u>k>;</u> Akihiko Hirose <akihikoh @dranihs. <u>net>;</u> <u>'Peter.Mar</u> sden@def ra.gsi.gov. <u>uk'</u> <<u>Peter.Ma</u> rsden@de fra.gsi.gov <u>.uk></u>; 'matsui@ eng.hokud ai.ac.jp' <matsui@ eng.hokud ai.ac.jp>; Ohanian, Edward

<Ohanian.

Edward@ epa.gov>; 'Ong Choon Nam' <ephocn @nus.edu <u>.sg></u>; Strong, Jamie <Strong.Ja mie@epa. gov>;

Testai

Emanuela

<emanuel

<u>a.testai@i</u>

ss.it>

Cc:

GORDON,

Bruce

Allan

<gordonb

@who.int

\geq Subject:

Re:

Seeking

feedback

on

atrazine +

other

updates.

Atrazine

is worth

another

look with

the latest

credible

informati

on. There

has

probably

been a

recent

review by

several

governme

nts

including

EPA's

Pesticides

unit.

On

3/19/2020 6:16 AM, DE FRANCE, Jennifer wrote:

Dear all

I hope this e-mail finds you healthy and well during these times.

I wanted to give you an update on a few things + seek your feedback:

 Atrazine: Bruce has received the attached letter (first) attachment) urging WHO to reconsider the guideline value for atrazine. The letter is signed by 33 scientists and health professionals. In line with our policies on pesticides evaluated by JMPR, the guideline value is based on their assessment which is from 2007. They note that the JMPR assessment is outdated and inadequately protective of public health and cite, inter alia, a report published by Public Eye (Jan 2020, second attachment), US EPA SAP Minutes 2011, US EPA Atrazine draft human health risk assessment for registration review 106 (2018, https://www.regulations.gov/document?D=EPA-HQ-OPP-2013-0266-1159), and several journal articles. The references they cite are included in the last two pages of the attached letter. Considering these more recent assessments, can you advise if you think atrazine should be re-assessed? If so, I can inform JMPR. Given atrazine is not authorized for use on food crops for international trade, it is likely that JMPR would only add to their workplan for reassessment if the request came from the Guidelines group. I understand that JMPR originally assessed atrazine in 2007 per the request from the Guidelines group. The atrazine background doc for the GDWQ + JMPR assessment can be accessed here.

2. Microplastics:

a. My food safety colleagues recently convened a meeting on the broader WHO work on microplastics and human health. A draft report has been prepared with the focus on food and air quality, but it was agreed that the literature on drinking-water should also be updated. While the data is limited, the aim is to conduct a preliminary risk assessment on total environmental exposure to microplastics including drinking-water. At this meeting, the value of the drinking-water report was recognized and I think this will be a highly useful resource to inform the broader report. They appreciated the careful wording re. the assessment on particle toxicity and would like to take a similar approach to the drinkingwater report in assessing chemicals associated with microplastics. So thank you to all of you for your technical input on the drinking-water report! I can seek your input on this wider report, particularly the drinking-water parts at key junctures. b. Todd Gouin who is leading the broader report, attended a GWRC meeting on microplastics and water in February on behalf of WHO. Attached is his report on the meeting + the GWRC final report on method harmonization and round robin comparison for

- 3. **Microcystin:** The <u>background document and public review</u> <u>form</u> are on our website for public review. There have been a few updates compared to the version I previously sent. Missing references were added + some updates on analytical aspects per feedback from Amanda Foss, who was one of the peer reviewers. I've attached the word version of the report for your info.
- 4. Other chemical documents. We are updating the other cyanotox docs now per public review feedback. I will share with you when this process is finalized. Several other documents are undergoing editing (TCE, PCE, organotins, nickel, iodine) while others are being updated per WG feedback (asbestos, manganese) or public review feedback (chromium). PFOS/PFOA is still being updated and will be shared with the working group when ready.

I have another query re. salinity and will follow up on that in a separate e-mail.

My best wishes to all of you and your families.

Jennifer

From: DE FRANCE, Jennifer Sent: 28 February 2020 14:43

Subject: Microcystin update

To: 'asami@niph.go.jp' <asami@niph.go.jp>;

'Carrier, Richard Ex. 6 Personal Privacy (PP) (HC/SC)' <richard.carrier@canada.ca>; Joseph Cotruvo (AoI) Ex. 6 Personal Privacy (PP) >; 'Cunliffe, David (Health) (David.Cunliffe@sa.gov.au)' <David.Cunliffe@sa.gov.au>; DAnglada, Lesley <DAnglada.Lesley@epa.gov>; Eckhardt Dr., Alexander <<u>Alexander.Eckhardt@uba.de></u>; 'john.fawell@johnfawell.co.uk' <john.fawell@johnfawell.co.uk>; Akihiko Hirose akihikoh@dranihs.net; 'Peter.Marsden@defra.gsi.gov.uk' <Peter.Marsden@defra.gsi.gov.uk>; 'matsui@eng.hokudai.ac.jp' <matsui@eng.hokudai.ac.jp>; Ohanian, Edward <Ohanian.Edward@epa.gov>; 'Ong Choon Nam' <ephocn@nus.edu.sg>; Strong, Jamie <Strong.Jamie@epa.gov> Cc: 'andrew.humpage@bigpond.com' <andrew.humpage@bigpond.com>; Testai Emanuela <emanuela.testai@iss.it>; ingrid chorus Ex. 6 Personal Privacy (PP) GORDON, Bruce Allan <gordonb@who.int>

I'm pleased to share with you the updated microcystin document. Please find attached the track changes version with comments (from peer reviewers, responses to peer reviewers, comments for editor, etc.), a clean version (with outstanding comments on references and comments for the editor retained), as well as a comment log with our key questions for peer reviewers, responses from peer reviewers and Andrew's responses.

The document has been updated following peer review feedback with a sincere thanks to Andrew, Emanuela and Ingrid.

A significant amount of feedback was provided during the peer review period with corresponding updates. Updates address:

- Addition of key missing studies, particularly in the sections on metabolism, elimination and DART. While a lot of track changes in the ADME section, there isn't a lot new in what is written, although as mentioned, the document was updated to address some newer studies on metabolism and elimination in particular.
- Comments on adding details on some tox studies
- To align better with the nearly finalized revised Toxic Cyanobacteria in Water (TCIW)
- To increase the robustness in the rationale for not including a database UF for the short-term GV

Peer reviewers were Alan Boobis (DART expert and very familiar with WHO guidelines processes), Sue Barlow (DART expert and very familiar with WHO guidelines processes), Bette Meeke (RA methodology expert and familiar with WHO guidelines processes), Ian Falconer (cyanotox expert), Dan Dietrich (cyanotox expert), Ludek Blaha (cyanotox expert), Neil Chernoff (cyanotox expert) and Amanda Foss (cyanotox expert recommended by Neil for ADME). Please see the attached comment log re. peer reviewer's specific responses with respect to our key questions including the questions on guideline value derivation. This includes the question on consideration of the DART studies. In summary, of the 6 experts who commented on whether DART studies warrant inclusion of a database UF for the short-term GV, 4 stated "no" including the DART experts, 1 "yes" and another noted that input from DART experts was needed since rationale for lack of inclusion of the database UF was weak. Given that additional DART papers were identified (from the same University as the prior debated studies), after the initial round of peer review, we sought further feedback from Alan and Sue on these studies. We also asked them to reconsider their opinion that no database UF was needed for the short-term GV based on additional studies identified in the metabolism, elimination and DART sections. They both agreed that even with these additional studies, no database UF was needed for the short-term value. Sue however recommended a different rationale for why no DB UF was included for the short-term value and the authors have updated this section to reflect her comments.

We will proceed with public review of this document shortly. As a reminder, this is the process that has taken place thus far for MC:

- The TCIW meeting in Singapore in 2016 agreed that a database UF was not necessary for the short-term guideline value which was reaffirmed at the chemical working group in Berlin in 2017 with the exception of two working group members.
- A teleconference was convened in January 2018 to further discuss the need for the database UF. WG members maintained their opinions on the database UF.
- At the July 2018 meeting, a formal voting system took place since consensus on this issue was not achieved at this meeting. The voting system was in line with process approved by the WHO Guidelines Review Committee (GRC) for the development of the 1st and 2nd addendum of the 4th edition of the GDWQ, which is based on the GRC handbook. The voting process concluded that a short-term provisional health-based guideline value for MC-LR was needed and no database UF was needed. However, given that consensus was not reached during the derivation of the short-term provisional health-based guideline value, WHO will draw specific attention to this fact during the peer review process and explicitly seek targeted feedback as to whether an UF needs to be applied to take into account data gaps.
- Peer review feedback and revision of the background document Oct 2019-Feb 2020. WG members were asked to propose peer reviewers. WHO also sought input from colleagues in food safety and chemical safety. Peer reviewers were selected based on their expertise, ensuring the following areas were covered: RA methodology, WHO guidelines derivation process, DART and MC. Peer reviewers were provided the background document and a peer review form with specific questions on guideline derivation including the DART studies.

Next steps

- Finalize document to put out for public review (removing comments, addressing outstanding reference issues if addressed quickly, etc.)
- · Public review for six weeks
- Finalize the document based on public review feedback and any other feedback received during this time period.

Best regards

Jennifer